

K031209

MAY 23 2003



GE Medical Systems

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General Electric Company
P.O. Box 414, Milwaukee, WI 53201

510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

Submitter: GE Medical Systems
PO Box 414 (W-400)
Milwaukee, WI 53201

Contact Person: Larry A. Kroger Ph.D.
Manager, Regulatory Programs

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Date Prepared: April 16, 2003

Device Name:

GE 1.5T 8 Channel Torso Coil
Magnetic Resonance Coil, 21 CFR 892.1000, 90-MOS

Marketed Device:

The GE 1.5T 8 Channel Torso Coil is substantially equivalent to the currently marketed GE the 3.0T Torso Phased Array Coil (K030495) with the integration of the 8 channel technology in the currently marketed GE 8 Channel Cardiac Phased Array Coil (K022669).

Device Description:

The GE 1.5T 8 Channel Torso Coil is a 12 element coil with integrated preamplifiers that provides optimized geometry for parallel imaging. The coil is designed to provide imaging of the abdomen, pelvis and chest regions. The device utilizes technology similar to the GE 8 Channel Cardiac Phased Array Coil (K022669), but is designed to image the torso, similar to the GE 3.0T Torso Phased Array Coil (K030495).

Indications for Use:

The GE 1.5T 8 Channel Torso Coil is intended to be used in the abdomen, pelvis and chest regions for 2D and 3D Magnetic Resonance imaging and Parallel body imaging.



Comparison with Predicate Device:

The GE 1.5T 8 Channel Torso Coil is a modification of the GE 3.0T Torso Phased Array Coil (K030495), which presents an increase in the number of coil elements from four to twelve, and integrates the preamplifiers similar to the GE 8 Channel Cardiac Phased Array Coil (K022669). The GE 1.5T 8 Channel Torso Coil utilizes optimized geometry for parallel imaging (ASSET).

Summary of Studies:

Testing was performed to demonstrate that the design of the 1.5T 8 Channel Torso Coil meet predetermined acceptance criteria.

Conclusion:

It is the opinion of GE that the GE 1.5T 8 Channel Torso Coil is substantially equivalent to the GE 3.0T Torso Phased Array Coil (K030495), and the GE 8 Channel Cardiac Phased Array Coil (K022669). The usage of the GE 1.5T 8 Channel Torso Coil does not result in any new potential hazards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2003

Larry Kroger, Ph.D.
Regulatory Programs Manager
GE Medical Systems
P.O. Box 414
MILWAUKEE WI 53201

Re: K031209
Trade/Device Name: GE 1.5T 8 Channel
Torso Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance
diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: April 16, 2003
Received: April 17, 2003

Dear Dr. Kroger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

KO31209

510(k) Number (if known): _____

Device Name: GE 1.5T 8 CHANNEL TORSO COIL

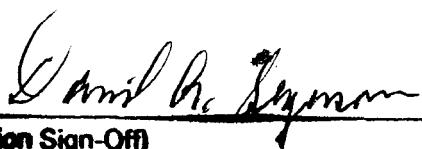
Indications For Use:

The GE 1.5T 8 Channel Torso Coil is intended to be used in the abdomen, pelvis and chest regions for 2D and 3D Magnetic Resonance imaging and Parallel body imaging

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)


(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number _____

KO31209